Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/538,061	**Applicant(s)** HARAGUCHI ET AL.	
	Examiner LEZAH W. ROBERTS	**Art Unit** 1612	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 12 August 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____months from the mailing date of the final rejection.
   b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): The 102 rejection anticipated by Busciglio.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *15-20 and 22-35*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☒ Other: 892.

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612

/Lezah W Roberts/
Examiner, Art Unit 1612

Continuation of 11. does NOT place the application in condition for allowance because: In regards to THUT, the reference suggests mixing a combination of an amide-type local anesthetic and an antihistamine-like anesthetic when it discloses that these two types of compounds may be mixed together (col. 3, lines 40-50). Furthermore Applicant has not asserted unexpected results that would show that the mixture is not obvious to one of ordinary skill in the art. The claims are also broad insofar as they read on any local anesthetic and any antihistamine. Although the claims of the reference focus on mixtures of amide-type anesthetic, the specification encompasses mixtures of amide-type anesthetics as well as amide-type anesthetics with antihistamine anesthetics. The support for the statement that osmotic pressure ratio controls absorption of a drug is supported by "an enhanced absorption of a drug through the mucosa by controlling the osmotic pressure of a pharmaceutical preparation is disclosed" (paragraph 0011 of Nishibe et al.). Applicant's arguments on page 10 of the remarks appear to further support the statement that the absorption is dependent on osmotic pressure. It would take no more than routine optimization to determine the effective osmotic pressure for the desire drug combination. In regards to the 1:1 ratio, the amount of drug used is a result effect variable and therefore it would take no more than ordinary skill in the art to adjust the ratio of the two drugs to yield effective results.

In regards to Takeuchi, it is obvious that the weight ratio of two drugs is a result effective variable because this determines the dosage of the drugs to a subject. One of skill in the art would adjust this ratio to determine the effective dosage for a subject. Furthermore even if this was not the case, the drugs are incorporated into the compositions at concentrations ranging from 0.001% to about 10% by weight. The combination of two drugs within these weight percents encompasses the ratio range of the instant claims. In regards to the why one of ordinary skill in the art would want to inject a composition with thermosetting gelation at body temperature for dental treatment or oral surgery, one would be motivated to inject these types of compositions because they can be easily administered or spread on the region to be treated in a fixed amount since it has good fluidity at room temperature or lower, and moreover, since it forms gel immediately after administration, it can keep a good residence of drugs in any regions and maintain a prolonged effect of drugs. One would inject the compositions because this is a method disclosed by the art as a method of delivering anesthetics (Watt-Smith US 4,659,714, col. 4, lines 32-40). Furthermore the instant claims recite "the composition is suitable for injection". The compositions of the reference are aqueous solutions and therefore are suitable for being injected to the target area.